HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

m2586n

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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PURGED ML 5/4/99

May 3, 1999

WARNING LETTER

NWE–22–99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James Stavis, President
North Coast Seafoods
12–14 Fargo Street
Boston, MA 02219

Dear Mr. Stavis:

On February 1–4, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 12–14 Fargo Street, Boston, MA. The inspection revealed that the fresh tuna and imported cod being processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The adulteration is due to deviations from the regulation governing procedures for the safe and sanitary processing and importing of fish and fishery products (seafood HACCP[1]), Title 21 Code of Federal Regulations, Part 123 (21 CFR § 123).

With respect to the processing of *imported cod*, the following deviations from HACCP regulations were noted:

- Documentation of affirmative steps is inadequate. For example, no written guarantee from the foreign processor for imported cod is maintained, as required under 21 CFR § 123.12(a)(2)(ii)(D). Your foreign processor has apparently completed a hazard analysis worksheet for cod and concluded that there are no food

[1] Hazard Analysis Critical Control Point. HACCP entails (1) identifying food safety hazards that, in the absence of appropriate controls, are reasonably likely to occur in your products and (2) having these controls at "critical control points" during processing to eliminate or minimize the likelihood that the identified hazards will occur.

safety hazards that are reasonably likely to occur with this product. However, no written guarantee to this effect has been obtained.

- Product specifications—designed to ensure that your firm's imported fresh cod fillets have been processed in accordance with Seafood HACCP—have not been developed. This is a requirement under 21 CFR § 123.12(a)(2)(i).

With respect to the processing of *fresh tuna*, the following deviations from the HACCP regulation were noted:

- Your firm listed an inappropriate corrective action in the HACCP plan for instances when tuna is suspected of being time / temperature abused at refrigerated storage. Therein, you propose to employ only a sensory (organoleptic) evaluation of the tuna. A sensory evaluation will not determine elevated histamine that may result under that circumstance. Therefore, a failure to account for possible elevated histamine when tuna has passed the sensory evaluation is a violation of 21 CFR § 123.7(a)(1).

- The monitoring of the refrigerator temperature while products are under refrigerated storage deviates regularly from your HACCP plan, which calls for checking the refrigerator temperature twice each day (once in the morning prior to production and once after lunch). The temperature has thus far only been recorded twice daily during the work week, and has not been recorded at all during the weekends. Personnel in the plant on weekends reportedly check the operation of the cooler, but have not been recording these checks on the *Product Storage Report* sheets. These practices are in violation of 21 CFR § 123.6(b).

The deviations identified above are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure that your firm and its products are in compliance with applicable regulations and laws enforced by FDA. Until your firm has achieved compliance with the seafood regulation, FDA will not issue any certificates for export for any seafood products processed at your facility.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by FDA without further notice. These actions may include seizure or injunction under the FD&C Act. Although your firm does not currently ship seafood to the European Union (EU), these violations of the FD&C Act may affect a future decision to do so, because your ability to obtain EU Certificates may be affected, or your firm may be removed from the EU list until FDA concludes that the deficiencies mentioned above have been satisfied.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, MA 02180. If you have any questions concerning this notice, please contact Mr. Lookabaugh at ***781.279.1675 x118.***

Sincerely,

John R. Marzilli
Director
New England District

cc:
Norman Stavis
North Coast Seafoods
12–14 Fargo Street
Boston, MA 02219